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Supreme Court, U.S.
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No. 91-

IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

LEDERLE LABORATORIES, Division Of American Cyanamid Company,

Petitioner,

v.

CAROL ANN FELDMAN,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF NEW JERSEY

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QUESTION PRESENTED

Whether the Supremacy Clause prohibits a state from imposing tort liability for failure to provide a warning when (a) federal law did not allow the warning to be given without approval of a federal agency, and (b) the federal agency had explicitly disapproved the warning.

PARTIES TO THE PROCEEDING

Petitioner is Lederle Laboratories, an unincorporated division of American Cyanamid Company. Respondent is Carol Ann Feldman. American Cyanamid Company has no parent company and only one non-wholly-owned domestic subsidiary, Applied Solar Energy Corporation.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDING	ii
TABLE OF AUTHORITIES	v
OPINIONS BELOW	1
JURISDICTION	2
CONSTITUTIONAL PROVISION, STATUTES, AND REGULATIONS INVOLVED IN THE CASE	2
STATEMENT OF THE CASE	3
REASONS FOR GRANTING THE PETITION	8
I. THE DECISION OF THE NEW JERSEY SUPREME COURT CONFLICTS DIRECTLY WITH DECISIONS OF U.S. COURTS OF APPEALS AND THIS COURT INTERPRETING THE SUPREMACY CLAUSE	9
II. EACH OF THE NEW JERSEY SUPREME COURT'S THREE WAYS OF EVADING THE FORCE OF FDA LABELING REQUIREMENTS WOULD SUBORDINATE FEDERAL LAW AND POLICY TO STATE LAW AND POLICY IN CLEAR VIOLATION OF THE SUPREMACY CLAUSE	12
A. The Fact That A Manufacturer Could Avoid Conflicting Federal And State Requirements By Going Out Of Business Does Not Eliminate The Preemptive Effect Of Federal Law	12
B. The Fact That Federal Authorities Might Not Choose To Bring An Enforcement Action Does Not Eliminate The Preemptive Effect Of Federal Law	14

C. The Fact That Petitioner Could Comply With Federal Law But Pay State Tort Damages For Doing So Does Not Eliminate The Preemptive Force Of Federal Law 17

CONCLUSION 20

TABLE OF AUTHORITIES

Cases:	Page
Animal Legal Defense Fund v. Provimi Veal Corp., 626 F.Supp. 278 (D. Mass.), *aff'd without opinion*, 802 F.2d 440 (1st Cir. 1986)	9
Baird v. General Motors Corp., 654 F. Supp. 28 (N.D. Ohio 1986)	18
Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691 (1984)	14
Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co., 450 U.S. 311 (1981)	11,18,19
Cipollone v. Liggett Group, Inc., 789 F.2d 181 (3d Cir. 1986), *cert. denied*, 479 U.S. 1043 (1987)	18
Cipollone v. Liggett Group, Inc., 893 F.2d 541 (3d Cir. 1990), *cert. granted*, 111 S. Ct. 1386 (1991), *argued*, 60 U.S.L.W. 3278 (Oct. 8, 1991), *restored to calendar for reargument*, Order List (Oct. 21, 1991)	7
City of New York v. FCC, 486 U.S. 57 (1988)	16
Cosmetic, Toiletry & Fragrance Association v. State of Minnesota, 440 F.Supp. 1216 (D. Minn. 1977), *aff'd*, 575 F.2d 1256 (8th Cir. 1978)	10
Dewey v. R.J. Reynolds Tobacco Co., 121 N.J. 69, 577 A.2d 1239 (1990)	7
Exxon Corp. v. Hunt, 475 U.S. 355 (1986)	16
Farmers Education & Cooperative Union v. WDAY, 360 U.S. 525 (1959)	19
Feldman v. Lederle Laboratories, 97 N.J. 429, 479 A.2d 374 (1984)	2,19
Ferebee v. Chevron Chemical Co., 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984)	7,17

Table of Authorities Continued

	Page
Fidelity Federal Savings & Loan Association v. de la Cuesta, 458 U.S. 141 (1982)	13,14,16
Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132 (1963)	11,16
Free v. Bland, 369 U.S. 663 (1962)	11
Grocery Manufacturers of America, Inc. v. Gerace, 755 F.2d 993 (2d Cir.), *aff'd mem.*, 474 U.S. 801, *cert. denied*, 474 U.S. 820 (1985)	10
Hillsborough County v. Automated Medical Laboratories, Inc., 471 U.S. 707 (1988)	11
Hines v. Davidowitz, 312 U.S. 52 (1941)	11
Hurley v. Lederle Laboratories Division of American Cyanamid Co., 851 F.2d 1536, *modified*, 863 F.2d 1173 (5th Cir. 1988)	7,9,10
Kordel v. United States, 335 U.S. 345 (1948)	3
Papas v. Upjohn Co., 926 F.2d 1019 (11th Cir.), *petition for cert. filed*, 59 U.S.L.W. 3825 (U.S. May 29, 1991) (No. 90-1837)	7,8,9,10,17
San Diego Building Trades Council v. Garmon, 359 U.S. 236 (1959)	18
Shakil v. Lederle Laboratories, 561 A.2d 511 (1989)	18
Constitutional Provision:	
Article VI, Clause 2	2
Statutory Provisions:	
7 U.S.C. §§ 136-136y	10
21 U.S.C. § 321(m)	3
21 U.S.C. § 332(a)	4
21 U.S.C. § 333(a)	4
21 U.S.C. § 334(a)(1)	4
21 U.S.C. § 352(*l*)	4

Table of Authorities Continued

	Page
21 U.S.C. § 357	3
21 U.S.C. § 357(a)	3
28 U.S.C. § 1257(a)	2
Rules and Regulations:	
21 C.F.R. § 130.1, *et seq.* (1963)	2
21 C.F.R. § 130.9(a) (1960)	3
21 C.F.R. § 146 (1963)	3
21 C.F.R. § 146.1 *et seq.* (1963)	3
21 C.F.R. § 146.4(b)(2) (1963)	4
Miscellaneous	
30 Fed. Reg. 993-94 (1965)	4
50 Fed. Reg. 7,452 (1985)	13
50 Fed. Reg. 7,515 (1985)	4

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CAROL ANN FELDMAN,
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PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF NEW JERSEY

Lederle Laboratories, a division of American Cyanamid Company, respectfully prays that a writ of certiorari issue to review the judgment of the Supreme Court of New Jersey.

OPINIONS BELOW

The opinion of the Supreme Court of New Jersey in *Feldman v. Lederle Laboratories, a Division of American Cyanamid Co.* is reported at 125 N.J. 117, 592 A.2d 1176 (N.J. 1991); the opinion is set forth in the Appendix at 1a. The opinion of the New Jersey Superior Court, Appellate Division, is reported at 234 N.J. Super. 559, 561 A.2d 288 (N.J. Super. Ct. App. Div. 1989); it is set forth in the Appendix at 72a.

The opinions were rendered after the second trial of this case in the Superior Court, Law Division, Essex County, New Jersey. The first trial had resulted in a verdict for petitioner. The Superior Court, Appellate Division, affirmed that judgment in an opinion reported at 189 N.J. Super. 424, 460 A.2d 203 (N.J. Super. Ct. App. Div. 1983), and the Supreme Court of New Jersey reversed and remanded for a new trial in an opinion reported at 97 N.J. 429, 479 A.2d 374 (N.J. 1984).

JURISDICTION

The judgment of the Supreme Court of New Jersey was entered on July 24, 1991. The Court's jurisdiction is invoked under 28 U.S.C. § 1257(a) (1988).

CONSTITUTIONAL PROVISION, STATUTES, AND REGULATIONS INVOLVED IN THE CASE

U.S. Constitution, Article VI, Clause 2:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

The pertinent provisions of the applicable sections of the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-393 (1988), and of the applicable regulations of the United States Food and Drug Administration adopted pursuant to the Act, *see* 21 C.F.R. § 130.1,

et seq. (1963); 21 C.F.R. § 146.1, *et seq.* (1963), are set forth in the Appendix at 111a - 120a.

STATEMENT OF THE CASE

The manufacture and distribution of prescription drugs in the United States is regulated under the FD&C Act and regulations promulgated by the Food and Drug Administration ("the FDA") under that act. These regulations provide detailed controls over the permissible "labeling" of all drug products. Under the FD&C Act, labeling is defined broadly to include "all labels and other written, printed, or graphic matter" upon the package of the drug or "accompanying such article." 21 U.S.C. § 321(m). Information that "supplements or explains" the original labeling is itself labeling, and "[n]o physical attachment one to the other is necessary." *Kordel v. United States*, 335 U.S. 345, 350 (1948).

During the time relevant to the claim asserted by respondent in this case, manufacturers of prescription drugs were not permitted to change the labeling of their products without prior FDA approval. 21 C.F.R. § 130.9(a) (1960). Under this regulation, if a labeling change were implemented without prior FDA approval, the manufacturer's new drug application could be suspended by the agency "on the grounds that it contains an untrue statement of material fact." *Id.*

Antibiotics, including the drug at issue in this case, were and still are subject to additional statutory and regulatory controls. *See* 21 U.S.C. § 357 (1988), 21 C.F.R. § 146 (1963) (currently codified at 21 C.F.R. § 430 (1991)). Before any batch of an antibiotic could be distributed lawfully, it had to be "certified," 21 U.S.C. § 357(a); if a batch were distributed without

a valid certificate, it would be deemed misbranded under the express terms of the FD&C Act, 21 U.S.C. § 352(*l*), and the manufacturer would be subject to a range of civil and criminal penalties. *See* 21 U.S.C. §§ 332(a), 333(a), 334(a)(1). A batch of an antibiotic that was initially certified by the FDA for distribution to the public with approved labeling would subsequently come to be misbranded if the "label or labeling [were] altered . . . or cease[d] to conform to any labeling requirement prescribed by the regulations." 21 C.F.R. § 146.4(b)(2) (1963). Accordingly, a manufacturer that made an unapproved change in the labeling of a certified batch of an antibiotic would be subject to a federal enforcement action for distributing a misbranded drug.[1]

Beginning in 1959, petitioner introduced to the market an antibiotic with the trade name Declomycin®, which is in the family of tetracyclines used to treat bacterial infections.[2] Pet. App. 3a. Between 1960 and 1963, when respondent was a small child, her physician-father treated her with Declomycin two or three times a year for various illnesses. *Id.* During that time, the approved label for Declomycin did not include a warning that tooth discoloration was a pos-

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[1] Although the drug and antibiotic regulations were subsequently amended to permit the addition of certain warnings to labeling without prior FDA approval, *see* 30 Fed. Reg. 993-94 (1965); 50 Fed. Reg. 7,515 (1985), those amendments were not in effect when the claim in this case arose. Even under the current regulations, once the FDA has made a determination about the use of a warning, a manufacturer does not have the freedom to ignore that determination without exposing itself to severe penalties under the FD&C Act.

[2] The generic name for the active ingredient in Declomycin is demethylchlortetracycline, a derivative of chlortetracycline.

sible side-effect of taking the antibiotic. Respondent claimed that her permanent teeth became discolored as the result of her use of Declomycin. Pet. App. 4a. Respondent claimed further that, during the period that she used the Declomycin, petitioner knew or should have known that tooth discoloration was a possible side-effect, but nevertheless failed to provide such a warning. *Id.*

After a trial in state court, the jury found that, although petitioner had no reason to know of this side-effect when respondent first ingested Declomycin, petitioner subsequently became aware of it in 1962 and, under New Jersey common law, petitioner should have provided a warning at that time. Pet. App. 2a. The jury also found that petitioner's failure to provide a timely warning was the proximate cause of respondent's injuries and awarded her damages of $300,000. *Id.*

At trial, petitioner did not deny that it was aware in November 1962 of the literature and anecdotal reports suggesting that the use of certain tetracyclines during tooth development might cause discoloration of the teeth. Petitioner's principal defense was that, despite its knowledge of these reports, petitioner was precluded by federal law from issuing any warning to treating physicians without the prior approval of the FDA and that the FDA had refused to give such approval. It was undisputed that petitioner communicated with the FDA about the possibility of a link between the use of tetracyclines and tooth discoloration once that information became available. Petitioner asked the FDA to approve a warning about tooth discoloration, but, although the FDA approved such a warning for other tetracyclines, the agency

specifically declined to do so as to Declomycin. Indeed, in April 1963, after investigating reports for several months about the link between tooth discoloration and the ingestion of tetracyclines, the FDA announced publicly that "there is no evidence to date that . . . demethylchlortetracycline[] causes the discoloration." Pet. App. 8a. The FDA's decision regarding Declomycin remained in effect until December 1963. Pet. App. 11a.

Petitioner appealed the trial court's judgment to the Appellate Division, arguing that, under the Supremacy Clause, the requirement of FDA approval of a labeling change, together with the refusal of the FDA to grant such approval, preempted any state-imposed "duty to warn." The Appellate Division agreed. Pet. App. 74a. That court held that "under certain circumstances, such as presented here, federal law may preempt a discrete issue upon which liability is predicated because compliance with State decisional law would require federal law to be violated." *Id.* The Appellate Division found that (i) the "clear wording" of the applicable regulations required petitioner to obtain the FDA's approval before adding the desired warning to its Declomycin, Pet. App. 101a, (ii) the FDA had declined to give such approval during the very time for which the jury had found that the warning should have been given by petitioner, Pet. App. 105a, and (iii) there was no contention that petitioner had failed to provide the agency with all relevant information about the drug and tooth discoloration. Pet. App. 103a.

On petition for certification, the Supreme Court of New Jersey, with one dissent, reversed and held that the FD&C Act, the labeling regulations, and FDA's

implementation of those regulations in this case did not preempt respondent's claim under state tort law. The court ruled that, "in the absence of a clear and manifest purpose to preclude the traditional workings of the tort compensation system," Pet. App. 32a, there is no reason that petitioner's "literal[]" compliance with the federal labeling regulations should render it "immune from state tort liability for injuries caused by [its] products." *Id.* The court found that there was "not a sufficient basis on which to find a direct conflict between state and federal law," *id.*, because petitioner could have avoided whatever conflict existed had it (1) refrained from marketing Declomycin, Pet. App. 38a, (2) interpreted the regulations to accommodate state tort law, discounting the risk of an FDA enforcement action, Pet. App. 35a-36a, or (3) realized that it could comply with the federal law on the condition that it pay damages to plaintiffs injured by such compliance. Pet. App. 32a.

In ruling as it did, the New Jersey Supreme Court purported to follow the reasoning of the decision of the D.C. Circuit in *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984), and expressly rejected the rulings of the Fifth and Eleventh Circuits in *Hurley v. Lederle Laboratories Division of American Cyanamid Co.*, 851 F.2d 1536, *modified*, 863 F.2d 1173 (5th Cir. 1988), and *Papas v. Upjohn Co.*, 926 F.2d 1019 (11th Cir. 1991), *petition for cert. filed*, 59 U.S.L.W. 3825 (U.S. May 29, 1991) (No. 90-1837). *See* Pet. App. 32a. The court also invoked its own decision in *Dewey v. R.J. Reynolds Tobacco Co.*, 121 N.J. 69, 577 A.2d 1239 (1990), Pet. App. 36a, 37a, a case in conflict with *Cipollone v. Liggett Group*, 893 F.2d 541 (3d. Cir. 1990), *cert.*

granted, 111 S.Ct. 1386 (1991), *argued*, 60 U.S.L.W. 3278 (Oct. 8, 1991), *restored to calendar for reargument*, Order List (Oct. 21, 1991).

Justice Garibaldi dissented, stating that "[t]he majority's narrow view of this case and the role of the [FDA] prevent it from understanding the untoward implications its decision could have on the health of the many members of our society other than [respondent]." Pet. App. 44a. The dissent stated that the federal labeling requirements clearly were in conflict with the duty imposed by state tort law and that the majority's assumption that "tort liability judgments do not have a profound regulatory effect on the prescription drug market is naive." Pet. App. 63a. Justice Garibaldi emphasized that "[t]he FDA cannot fulfill its role [as a promotor and protector of public health] if state courts are allowed to require certain actions by pharmaceutical manufacturers that are prohibited under federal law and that supplant, rather than supplement, the carefully-considered regulations of a federal government agency." Pet. App. 45a.

REASONS FOR GRANTING THE PETITION

The New Jersey Supreme Court held that petitioner must pay damages for failure to provide a warning that (i) was not permitted by federal law without FDA approval and (ii) was expressly considered and disapproved by the FDA. The state court acknowledged that its ruling conflicted with decisions of two federal courts of appeals, one of which is pending on petition for a writ of certiorari.[3] It did not acknowledge that

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[3] *See Papas v. Upjohn Co.*, 926 F.2d 1019 (11th Cir.), *petition for cert. filed*, 59 U.S.L.W. 3825 (U.S. May 29, 1991) (No. 90-1837).

its ruling also conflicted with decisions of this Court interpreting the Supremacy Clause. Instead, it proposed three reasons for honoring state policy in preference to federal law, each of which would stand the Supremacy Clause on its head.

I. THE DECISION OF THE NEW JERSEY SUPREME COURT CONFLICTS DIRECTLY WITH DECISIONS OF U.S. COURTS OF APPEALS AND THIS COURT INTERPRETING THE SUPREMACY CLAUSE.

FDA regulations did not permit petitioner to add a warning to the "label" for Declomycin without FDA approval.[4] Petitioner had in fact proposed a tooth-discoloration warning for FDA approval, which the FDA had explicitly declined to grant.[5] Nevertheless, the New Jersey Supreme Court approved a jury award of damages to respondent on the ground that petitioner had violated a state law duty to warn respondent about tooth discoloration.

The state court acknowledged that its decision conflicted with two recent decisions of U.S. courts of appeals, *Hurley v. Lederle Laboratories*, 851 F.2d 1536, *modified*, 863 F.2d 1173 (5th Cir. 1989), and *Papas v. Upjohn Co.*, 926 F.2d 1019 (11th Cir. 1991), *petition for cert. filed*, 59 U.S.L.W. 3825 (U.S. May 29, 1991) (No. 90-1837). In both cases, the courts of appeals held correctly that "failure to warn" claims are preempted where the only warnings that would satisfy the state-law duty to warn are forbidden under a federal regulatory scheme.[6]

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[4] *See supra* pages 3-4.

[5] *See supra* pages 5-6.

[6] The state court's decision also conflicts with decisions of the First, Second, and Eighth Circuits. *See Animal Legal Defense*

Hurley involved requirements under the FDA's regulations relating to vaccines that are essentially identical to the requirements for antibiotics at issue in this case: the FDA's labeling regulations at issue there (like the regulations here) required the FDA's prior approval of new or altered warnings. 863 F.2d at 1179 (citing 21 C.F.R. § 601.12). The court of appeals held that a "state law determination [that a drug warning was inadequate] should not be interjected to overrule the decision of the FDA. Such a procedure would place vaccine manufacturers in a position where they could not comply with both obligations." *Id.*

Papas involved the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (1988), which imposes a similar requirement of federal approval of label contents, including warnings. The court of appeals held that a jury verdict that the defendant had given an inadequate warning on its pesticide was preempted by federal law, in view of the Environmental Protection Agency's prior determination that

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Fund v. Provimi Veal Corp., 626 F. Supp. 278 (D. Mass.), *aff'd without opinion*, 802 F.2d 440 (1st Cir. 1986) (state consumer protection act suit challenging warning on veal products held preempted by federal regulation of meat labeling and medicated animal feeds); *Grocery Mfrs. of America, Inc. v. Gerace*, 755 F.2d 993 (2d Cir.), *aff'd mem.*, 474 U.S. 801 (1985) (compliance with state labeling requirements regarding use of term "imitation" would subject manufacturer to liability for misbranding under federal regulations and thus was preempted), *cert. denied*, 474 U.S. 820 (1985); *Cosmetic, Toiletry & Fragrance Ass'n v. State of Minnesota*, 440 F. Supp. 1216, 1223 (D. Minn. 1977), *aff'd*, 575 F.2d 1256 (8th Cir. 1978) ("when federal agencies have perceived a specific risk and have required labeling to alleviate that risk . . . a state's freedom to require other than identical labeling with respect to that risk is precluded").

the defendant's warning was adequate. *See* 926 F.2d at 1024-25.

A state-law labeling requirement that conflicts with a federal requirement is, of course, preempted. As the state court recognized here, state law is preempted when "'compliance with both federal and state regulations is a physical impossibility[.]'" Pet. App. 17a (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963)). Even if compliance with both is not physically impossible, state law is preempted if it "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Hillsborough County v. Automated Medical Lab., Inc.*, 471 U.S. 707, 713 (1985) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). As the state court also recognized, valid federal regulations, such as the FDA's regulations here, have the same preemptive effect as federal statutes. *See* Pet. App. 16a (citing *Hillsborough County v. Automated Medical Lab., Inc., supra*; *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 325-26 (1981)). And as the state court acknowledged, where there is a conflict between state and federal law, the importance of the state policy is immaterial and "'the federal law must prevail.'" Pet. App. 17a-18a (quoting *Free v. Bland*, 369 U.S. 663, 666 (1962)).

Although it accurately recited the law of preemption, the state court evaded its force in this case with three arguments, each of which, on examination, subordinates federal law and policy to state law and policy in clear violation of the Supremacy Clause.

II. EACH OF THE NEW JERSEY SUPREME COURT'S THREE WAYS OF EVADING THE FORCE OF FDA LABELING REQUIREMENTS WOULD SUBORDINATE FEDERAL LAW AND POLICY TO STATE LAW AND POLICY IN CLEAR VIOLATION OF THE SUPREMACY CLAUSE.

The state court suggested three techniques that petitioner could have used to comply with its duty to warn under state law without actually violating federal law. First, petitioner could have stopped marketing Declomycin for pediatric use, abandoning the business that subjected it to inconsistent regulatory commands. Second, the court suggested that petitioner should have tried harder to convince the FDA to change its mind. If it failed to do so, according to the court, petitioner should have ignored what the FDA had said to it, published the additional warning, and taken a chance on an enforcement action, which the court asserted was not likely to be pursued by the FDA. Third, the court said that petitioner could always comply with the federal regulations, omit the warning imposed by the state tort law, and pay damages to state plaintiffs. *See* Statement of Case, *supra*, at 7. Each of these "solutions" does indeed show that, in a literal sense, it was not "physically impossible" to avoid violating either federal or state law, but each of them rides roughshod over federal policy to promote the sale of safe, effective drugs in an FDA-approved manner.

A. The Fact That A Manufacturer Could Avoid Conflicting Federal And State Requirements By Going Out Of Business Does Not Eliminate The Preemptive Effect Of Federal Law.

The state court's suggestion that petitioner could have avoided the inconsistent commands of federal

and state law by abandoning this line of business is at once correct and absurd. While complying with both federal and state law by going out of business is of course not physically impossible, the purpose and objective of Congress in permitting the sale of drugs under labels deemed proper by the FDA would clearly be frustrated if a state were free to drive a manufacturer out of business by setting up a conflicting regulatory scheme.

As Justice Garibaldi said in dissent, the FDA has the explicit mandate "'to act as *both* a public health *promoter* by facilitating the approval of important new safe and effective therapies, *and* as a public health *protector*, by keeping off or taking off the market drugs not shown to meet safety and efficacy standards.'" Pet. App 45a (quoting 50 Fed. Reg. 7,452 (1985)) (emphasis supplied by Justice Garibaldi). Justice Garibaldi noted that the effect of the state court's decision would be to bar the sale, on grounds of improper labeling, of a product that *federal* law deemed properly labeled. That is a clear subordination of federal labeling policy to state policy, in violation of the Supremacy Clause.

In virtually every conflict preemption case involving regulation of an industry, the regulated entity would avoid the conflict by going out of business. For example, in *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141 (1982), the regulated federal savings institution could have avoided the conflict between federal regulations permitting "due-on-sale" clauses and state law prohibiting them by not lending money at all or by "voluntarily" omitting the clause that subjected the institution to the conflicting commands of state and federal law. The Court neverthe-

less found that state law was preempted. Similarly, the television cable operator in *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 706 (1984), could have avoided the conflict between the FCC's "must-carry" rules, which prohibited deleting or altering any portion of the broadcast signals carried by the cable operator, and state criminal law, which prohibited commercials about certain alcoholic beverages, simply by going out of the cable business. As in *Fidelity Fed. Sav. & Loan*, this Court held that the state law "compels conduct that federal law forbids," and was therefore preempted. *Id.*

B. The Fact That Federal Authorities Might Not Choose To Bring An Enforcement Action Does Not Eliminate The Preemptive Effect Of Federal Law.

The state court next suggested that petitioner could have tried harder to persuade the FDA to allow the warning and if necessary could have run the risk of federal enforcement if (as here) petitioner were unsuccessful. The court did *not* deny that federal law appeared to require prior FDA approval of warnings, but instead said that federal law did not "clearly" do so, Pet. App. 32a. The court therefore suggested that petitioner could have taken the chance that the federal law would not be enforced against it. Pet. App. 33a.

The preemptive force of federal law is not eliminated by the fact that the state court found "no evidence indicating that the FDA ever took" enforcement action for similar violations of the labeling regulations. *Id.* There was no basis for a finding that the federal requirement had fallen into desuetude here. To require a federally regulated manufacturer to defy a federal pre-approval requirement in order to comply

with a conflicting requirement of state law and risk an enforcement action by the federal agency that has expressly denied giving approval plainly violates the Supremacy Clause.[7]

The state court's suggestion that petitioner should have "continued to press for FDA approval of a warning for Declomycin after the administration's initial response declining to change its official position," Pet. App. 39a, is equally unavailing. Petitioner had concededly followed all required federal procedures to obtain the FDA's approval of the warning that New Jersey now says petitioner should have used. Petitioner had provided the FDA with all the information petitioner possessed that would support the approval of the proposed warning. The FDA said no, on the basis of a complete factual record. There were repeated communications between petitioner and the FDA about warnings that should accompany Declomycin, despite which the FDA took the position, as late as July 1, 1963, that, because there was no evidence that Declomycin causes discoloration of teeth, there was no justification for a "change in our current formal position" denying the need for the warning. Pet. App. 10a. The state had no right to determine that *its* policy barred petitioner from taking "no" for

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[7] The existence of a conflict for purposes of the Supremacy Clause does not turn on how frequently an administrative agency may exercise its prosecutorial prerogatives. Indeed, a conflict could exist even if, for some inexplicable reason, Congress enacted a federal regulatory scheme without investing a federal agency with enforcement powers. Moreover, the presence or absence of enforcement actions by any particular group of federal officials does not guarantee that different enforcement priorities might not be adopted by their successors. Preemption doctrine cannot turn on such ephemeral considerations.

a *federal* answer after all *federal* procedures were properly followed.

There is no substance to the state court's notion that the alleged lack of "clarity" of the federal commands makes them any less "supreme." A requirement of "clear statement," as was imposed by the state court, is quite properly incorporated into *express* preemption analysis, where the question is whether Congress actually intended to bar application of state law. *See, e.g., Exxon Corp. v. Hunt*, 475 U.S. 355, 362-70 (1986) (express preemption cases require courts to analyze congressional purpose when language of statute is not clear). But where the question is whether the mandates of federal regulation conflict with state law, *conflict* preemption analysis requires no inquiry into congressional intent. *City of New York v. FCC*, 486 U.S. 57, 64 (1988) ("in a situation where state law is claimed to be pre-empted by federal regulation, a 'narrow focus on Congress' intent to supersede state law [is] misdirected,' for '[a] pre-emptive regulation's force does not depend on express congressional authorization to displace state law'") (quoting *Fidelity Fed. Sav. & Loan*, 458 U.S. at 154). *See also Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. at 142-43. In conflict preemption cases, the only question is whether the federal requirement as *properly* interpreted is inconsistent with the requirement that the state seeks to impose. The fact that the authorized federal agency could conceivably have interpreted the federal statute differently is wholly irrelevant. State courts are not free to avoid a conflict by deciding that a federal agency's interpretation of its governing statute is wrong.

C. The Fact That Petitioner Could Comply With Federal Law But Pay State Tort Damages For Doing So Does Not Eliminate The Preemptive Force Of Federal Law.

The state court also suggested (as did the petitioner in *Cipollone*) that petitioner could have complied with both federal and state policies by adhering to federal "prior approval" requirements while paying damages in tort suits for failing to provide the warning prohibited by federal law. Pet. App. 36a. In reaching this conclusion, the court adopted the reasoning of the federal appeals court in *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984), Pet. App. 32a, a decision that has been rejected explicitly by the Eleventh Circuit in *Papas*, *supra*, and implicitly by other federal appellate courts,[8] and one which in effect rewrites the Supremacy Clause.

The court in *Ferebee* held that there is nothing inconsistent in allowing states to require defendants to pay tort damages for violating state law (the duty to provide adequate warnings in that case), even where state law conflicts with federal law, because tort damages are intended to compensate plaintiffs, not to regulate conduct. *Ferebee*, 736 F.2d at 1541. A damages suit, according to the D.C. Circuit and now the New Jersey Supreme Court, does not actually require a defendant to alter its conduct; it only requires the defendant to pay money when compliance with federal law results in personal injury.

These decisions ignore reality; damage awards under state tort law are intended to and do in fact regulate conduct. It is well settled that damage

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[8] *See supra* footnote 6.

awards are designed, in part, to reflect and define duties imposed by law, such as the duty of care or (here) the duty to warn. *See Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 325-26 (1981) (state-court damages action for failure to provide adequate rail service would compel conduct otherwise regulated by federal agency); *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959) (allowing state damage award would regulate conduct left to the primary jurisdiction of National Labor Relations Board); *see also Cipollone v. Liggett Group, Inc.*, 789 F.2d 181, 187 (3d Cir. 1986) ("effect" of allowing state liability for failure to provide additional warnings would be to interfere with federal "balance of purposes"), *cert. denied*, 484 U.S. 976 (1987); *Baird v. General Motors Corp.*, 654 F. Supp. 28, 32 (N.D. Ohio 1986) (state tort liability for failure to install air bags in automobiles would "force automobile manufacturers to choose the air bag option over other statutorily approved options"); *cf. Shakil v. Lederle Lab.*, 561 A.2d 511, 529 (1989) (market share liability on vaccine manufacturers would discourage vaccine production). This Court stated clearly in *Garmon*:

> Our concern is with delimiting areas of conduct which must be free from state regulation if national policy is to be left unhampered. Such regulation can be as effectively exerted through an award of damages as through some form of preventive relief. *The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.*

359 U.S. at 246-47 (emphasis added).

The payment of damages in a tort case occurs only when the defendant has violated a *duty* imposed by state law and the violation of that *duty* causes injury. The state law duty that was violated here, in the court's own words, was the "*duty* to warn of dangers of which [drug manufacturers] know or should have known on the basis of reasonably obtainable or available knowledge." Pet. App. 1a-2a (citing *Feldman v. Lederle Lab.*, 479 A.2d 374, 376 (N.J. 1984)) (emphasis supplied). But New Jersey is not free to impose that duty on petitioner because it is directly contrary to the duty imposed by federal law—*i.e.*, the duty to provide only those warnings that are authorized by the FDA and to refrain from using additional warnings disapproved by the agency. There can be no question that the two duties—the state duty to warn and the federal duty to provide only approved warnings—are in direct conflict. *Cf. Chicago & N.W. Transp. Co.*, 450 U.S. at 325-26 ("[i]t would vitiate . . . congressional intent . . . to permit the State of Iowa to use the threat of damages to require a carrier to do exactly what the Commission is empowered to excuse"); *Farmers Educ. & Coop. Union v. WDAY*, 360 U.S. 525, 531 (1959) (allowing respondent to maintain a slander suit "would sanction the unconscionable result of permitting civil . . . liability to be imposed for the very conduct the [federal] statute demands of the licensee"). When that is the case, the Supremacy Clause dictates that federal law shall prevail.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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